

PATENT  
674521-2001.1**REMARKS**

Reconsideration and withdrawal of the rejections of this application are requested.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-5, 10-14, 17, 19-21 and 35-51 are under examination in this application.

Claims 5, 10, 12-14, 17, 19 and 35 are amended; claims 7, 8, 15, 16 and 22-32, drawn to non-elected subject matter, are cancelled without prejudice. Applicants retain the right to file divisional applications to non-elected subject matter.

Support for the amendments can be found throughout the specification. Specifically, support for the recitation "nucleic acid molecule of interest" in claim 19 can be found on page 20, line 30, of the specification. Support for the nucleic acid molecule of interest being positioned between the terminal repeats can be found on page 21, lines 27 and 28. The remaining amendments have been made to address dependence and formal issues.

No new matter is added by these amendments.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. The herein amendments of and additions to the claims are not made for the purpose of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather, the amendments are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendments should not give rise to any estoppel, as the herewith amendments are not narrowing amendments.

**Drawings**

Applicants confirm that the drawings submitted on March 4, 2004 do not contain color elements. Acceptance of the formal drawings is requested.

**Claim Objections**

Claims 10, 11, 14, 17, 35, 36 and 51 were objected to under 37 CFR 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot be dependent upon another multiply dependent claim. Multiple dependencies have been removed from all claims, obviating the objection.

Claim 5 was objected to under 37 CFR 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot be dependent upon subsequent claims. Claim 5 has been rewritten in independent form, rendering this rejection moot.

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**II. THE REJECTIONS UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, ARE OVERCOME**

Claims 1-4, 12, 13, 19-21 and 37-50 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

Much of the focus of this rejection is directed toward the fact that the genus of nucleic acid molecules that hybridize to SEQ ID NO:3 or a nucleotide sequence having at least 95% identity to SEQ ID NO:3 is allegedly overly broad. The removal of hybridization language in the claims obviates the portion of the rejection made on this basis.

Independent claim 12 and dependent claims 1-410, 11, 14, 17 and 35-43 now encompass a retrotransposon having at least 95% sequence similarity with SEQ ID NO:3. The breadth of the claims has been modified such that one of ordinary skill could easily envision claimed genus of nucleic acids. To that end, the Examiner's attention is drawn to Example 14 of the USPTO's "Synopsis of Application of Written Description Guidelines". Example 14 presents a fact pattern that is analogous with that of the instant application. The claim in Example 14 recites the (1) the structure of the claimed molecule, in the form of a SEQ ID NO and variants with a particular percent identity to the recited sequence, and (2) function in the form of identifying the reaction that the protein catalyzes (i.e. its enzymatic activity). Claim 12 of the instant application recites (1) the structure of the claimed molecule in the form of a SEQ ID NO, and variants with at least 95% identity to the recited sequence, and (2) function of the claimed molecule in the form of its retrotransposon activity. As discussed in Example 14, even if the claimed SEQ ID NO is the only species disclosed, it is representative of the genus because all members of the genus have the claimed level of identity with and function of the molecule described by the reference sequence. Therefore, according to Example 14 of the Written Description Guidelines, claim 12, as presented herein, meets the written description requirement of 35 U.S.C. §112, first paragraph.

With respect to the rejection of claims 1-4 related to free copy number, it is believed that the removal of hybridization language in claim 12 addresses this rejection. If this is not the case, it is requested that the Examiner clarify the basis of this rejection.

Claims 1-4, 12, 13, 19-21 and 37-50 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

As discussed above, the hybridization language has been removed from the claims, addressing several of the issues raised in the Office Action. It is submitted that the only point of contention remaining with respect to Section 112, first paragraph considerations is the recitation

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of "95% sequence similarity". Applicants argue that no undue experimentation would be required on the part of the skilled artisan, particularly in view of the fact that claim 12 recites identity as high as 95%. To that end, the Examiner is respectfully reminded that the Court of Appeals for the Federal Circuit stated in the case of *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988):

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is **undue**, not **experimentation**. The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a **considerable amount of experimentation is permissible**, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ...  
[Emphasis added. Citations omitted]. *Id.* at 1404.

While the retrotransposon of SEQ ID NO:3 is novel, eukaryotic transposons have been known in the art since Barbara McClintock's work in the 1940s and 50s. Therefore, transposable elements have been well characterized, the state of the art is quite developed, and is not unpredictable, as is suggested in the Office Action. The guidance provided in the specification, along with the body of knowledge possessed by the artisan in this field, is sufficient for the invention to be practiced without undue experimentation.

In view of the foregoing, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

### III. THE REJECTIONS UNDER 35 U.S.C. § 112, 2<sup>nd</sup> PARAGRAPH, ARE OVERCOME

Claims 1-4, 13, 19-21 and 37-50 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The rejections are traversed.

Claim 13 has been amended to recite a cell that is transformed with TCa2, overcoming its rejection.

Claim 19(a) has been amended to clarify that any nucleic acid molecule can be used in the invention, provided it is positioned within the retrotransposon of the invention.

Hybridization language has been removed from claims 12 and 19, obviating their rejection on that basis.

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Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, are requested.

CONCLUSION

Applicants believe that the application is in condition for allowance, and favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. Alternatively, consideration and entry of this paper are requested, as it places this application into better condition for purposes of appeal.

Respectfully submitted,  
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